Section 2: 510(k) Summary (21 CFR § 807.92)

Submitter: Avinger, Inc.
400 Chesapeake Drive
Redwood City, CA 94063

AUG - 6 2010

Contact: Himanshu Patel
Chief Technology Officer

Date Summary Prepared: 15 July 2010

Device Trade Name: Wildcat 6F Guidewire Support Catheter

Common Name: Guidewire Support Catheter

Classification Name: Percutaneous Catheter (21 CFR § 870.1250)

Product Code: DQY

Cleared Device: Wildcat 7F Guidewire Support Catheter (K083313)

Device Description:

The Wildcat 6F Guidewire Support Catheter is a 6F sheath and 0.035" guidewire compatible over-the-wire device. It consists of a catheter shaft with handle assembly at the proximal end and an atraumatic distal tip. The catheter is available in two sizes with a working length of either 110 cm or 135 cm. A locking luer connector at the proximal end provides entry to a lumen that supports and facilitates movement of a guidewire. The catheter has been irradiated for sterility and is intended for single use only.

Intended Use:

The Wildcat 6F Guidewire Support Catheter is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline/contrast.

Nonclinical Performance Data:

Design verification testing was conducted. Such testing confirms that the Wildcat 6F device performs according to the stated intended use. Device evaluation consisted of laboratory testing specified in 10555-1 "Sterile, single-use intravascular catheters – Part 1 – General Requirements" and included tensile, torque strength, coating integrity and device compatibility. Biocompatibility testing was

conducted according to EN ISO 10993-1 "Biological Evaluation of Medical Devices". All data fell well within pre-determined product specifications and external standard requirements.

Comparison with Cleared Device:

The Avinger 6F catheter is very similar to the Avinger 7F catheter. Both devices are intended for use with steerable guidewires to access discrete regions of the peripheral vasculature. Additionally, both devices may be used to facilitate placement and exchange of conventional guidewires and to deliver saline or contrast. Both devices are comprised of similar materials and function according to similar operating parameters. There are three primary differences between the modified and cleared devices. First, the modified device has a smaller profile (6F as opposed to 7F) as compared to the cleared device. Second, the distal tip has been modified to allow for articulation. Lastly, the 6F device will be offered in two working lengths to accommodate various access procedures.

Summary:

Based upon the product technical information, intended use, and performance data provided in this premarket notification, the Avinger 6F catheter has been shown to be equivalent to the currently marketed Avinger 7F catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG - 6 2010

Avinger, Inc
c/o Mr. Himanshu Patel
Chief Technology Officer
400 Chesapeake Drive
Redwood City, CA 94063

Re: K102022
Trade/Device Name: Wildcat 6F Guidewire Support Catheter
Regulation Number: 21 CFR§ 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 16, 2010
Received: July 19, 2010

Dear Mr Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1: Statement of Indications for Use

510(k) Number if known: TBD K102022

AUG - 6 2010

Device Name: Wildcat 6F Guidewire Support Catheter

Indications for Use:

The Wildcat 6F Guidewire Support Catheter is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline/contrast.

Prescription Use: [X] **AND/OR** **Over-the-Counter Use** ____
(Per 21 CFR § 801, Subpart D) **(Per 21 CFR §807, Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102022